FDA Public Health Advisory

Suicidality in Adults Being Treated with Antidepressant Medications

Several recent scientific publications suggest the possibility of an increased risk for suicidal behavior in adults who are being treated with antidepressant medications. Even before these reports became available, the FDA began a complete review of all available data to determine whether there is an increased risk of suicidality (suicidal thinking or behavior) in adults being treated with antidepressant medications. It is expected that this review will take a year or longer to complete. In the meantime, FDA is highlighting that:

- Adults being treated with antidepressant medications, particularly those being treated for depression, should be watched closely for worsening of depression and for increased suicidal thinking or behavior. Close watching may be especially important early in treatment, or when the dose is changed, either increased or decreased.
- Adults whose symptoms worsen while being treated with antidepressant drugs, including an increase in suicidal thinking or behavior, should be evaluated by their health care professional.

These recommendations are consistent with existing warnings for treated adults in the approved labeling (package insert) for antidepressant medications that can be found at: http://www.fda.gov/cder/drug/antidepressants/PI template.pdf The Healthcare Professional and Patient Information Sheets for the antidepressant indications will be updated to add this information within the week. A list of drugs to be included in this update can be found at:

http://www.fda.gov/cder/drug/antidepressants/antidepressantList.htm

FDA is working closely with the manufacturers of all marketed antidepressants to fully evaluate the risk of suicidality in adults treated with these drugs. The FDA has asked these manufacturers to identify all placebo-controlled trials conducted in adults in their development programs for their antidepressant products, regardless of the indication studied, and to provide information from these trials to FDA. Manufacturers are being asked to use a similar approach to assembling this information as was used in evaluating the risk of suicidality in placebo-controlled trials in pediatric patients treated with antidepressant medications. The method used to analyze the data for risk of suicidality in children using antidepressant medications is described in more detail at the following web page: http://www.fda.gov/cder/drug/antidepressants/default.htm. A similar approach will be used for adults.

FDA's comprehensive review will involve many hundreds of individual clinical trials and many thousands of adult patients. It is expected that this review will require a year or more to complete because of the large number of trials and the thousands of adverse events that must be checked for possible evidence of suicidality. The FDA will make the results of its review available to the public once its analyses are complete, and will update this advisory in the meantime if more definitive information becomes available.